REMARKS

Status of the Application

Claims 29-36 and 38-61 are currently pending.

Specification Amendments

Applicants have amended the "Related Patent Application" information section on page 1 of the specification. Specifically, the prior recitation referred to the parent application, namely U.S. Application No. 08/814,974, but failed to include information regarding the prior applications from which U.S. Application No. 08/814,974 claimed priority. No new matter has been added as a result of this amendment.

Applicants have amended Table II, "Patient Study Lipid Profile Data", in order to correct typographical errors in the data. No new matter was added as a result of this amendment.

Claim Amendments

Claim 29 has been amended to recite that put the phrase "intermediate release" into the body of the claim. In addition, this claim has also been amended to remove the reference to the "dissolution curve similarity fit factor F2 of at least about 79". Moreover, this claim has also been amended to recite that the formulation comprises 1000 mg of nicotinic acid and a swelling agent. Support for "1000 mg of nicotinic acid" can be found in Table 9 on page 22. Support for the swelling agent can be found on page 24, beginning at line 16 – page 25, line 5.

Claims 31, 33, 39, 43, 45 and 47-61 have been amended. Claims 62 and 63 are new. Support for claims 62 and 63 can be found on page 24, beginning at line 16 – page 25, line 5.

No new matter has been added as a result of any of these amendments.

Double Patenting

Claims 29-36 and 38-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,080,428; claims 1-

148 of U.S. Patent No. 6,129,920[1]; claims 1-30 of U.S. Patent No. 6,469,035; claims 1-16 of U.S. Patent No. 6,406,715; claims 1-21 of U.S. Patent No. 6,746,691; claims 1-28 of U.S. Patent No. 6,818,229; and claims 1-12 of U.S. Patent No. 7,011,848. Applicants respectfully traverse.

Applicants wish to hold this rejection in abeyance until notification from the Examiner of allowable subject matter. Upon receipt of allowable subject matter, Applicants will take the necessary steps to remove this rejection.

The Examiner also notes that claims 29-36 and 38-61 are directed to an invention that is not patentably distinct from claims 1-13 of U.S. Patent No. 6,080,428; claims 1-148 of U.S. Patent No. 6,129,930; claims 1-30 of U.S. Patent No. 6,469,035; claims 1-16 of U.S. Patent No. 6,406,715; claims 1-21 of U.S. Patent No. 6,746,691; claims 1-28 of U.S. Patent No. 6,818,229; and claims 1-12 of U.S. Patent No. 7,011,848. The Examiner has asked Applicants to show that the above application is commonly owned with the above recited list of patents in order to preclude a rejection under 35 U.S.C. Section 103(a) in view of 35 U.S.C. Sections 102(e)-(g).

Applicants submit that the above application and all of the above listed patents are commonly owned. Specifically, as shown in attached Exhibit A, the above application is assigned to Kos Pharmaceuticals, Inc. The cover pages for U.S. Patent Nos. 6,080,428, 6,129,930 and 6,469,035 do not list an assignee. Exhibit B attached herewith is a copy of the US PTO assignment records, which shows that each of the above patents have been assigned to Kos Life Sciences, Inc. Applicants believe that this information is sufficient to respond to the Examiner's request. If the Examiner requires any additional information or has any questions regarding this matter, the Examiner is invited to contact the undersigned attorney.

Claim Rejections – 35 U.S.C. Section 112, First Paragraph

Claims 29-36 and 38-61 are rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement. The Examiner says that the claims recite a method of treating cholesterol disorders with an intermediate release composition comprising nicotinic acid that exhibits a specific dissolution profile. According to the Examiner,

[1] Applicant believes that the Examiner is referring to 6,129,930 and that this is simply a typographical error.

"[A] careful review of the specification only reveals that while instant dissolution profile is achieved with a composition, which is manufactured by wet granulation of hydroxypropyl methylcellulose, povidone and stearic acid. However, the instant claims broadly encompass any pharmaceutical delivery system that renders the claimed dissolution, which are not described in the instant specification". Applicants respectfully traverse.

As discussed in the *MPEP* Section 2163.04, the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. Specifically, this section of the *MPEP* states:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Id*

Applicants respectfully submit that the Examiner has not met her burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in Applicants' specification a description of the invention as defined by the claims as currently amended. Applicants submit that the specification provides an adequate written description that is commensurate with the scope of the claims. Specifically, claim 29, which is the only independent claim, has been amended to recite that the intermediate release formulation comprises 1000 mg of nicotinic acid and a swelling agent. The specification on page 24, beginning at line 16 – page 25, line 5 describes in detail the swelling agent that can be used to make the claimed formulation. A number of examples of swelling agents, such as carboxymethylcellulose, methylcellulose, waxes (such as bees wax), natural materials (like gums or gelatins) or mixtures thereof are provided. Thus, based on the above description contained in Applicants' specification, one skilled in the art would clearly recognize a description of the invention as defined by the currently pending claims. In view thereof, this rejection is now moot and should be withdrawn.

Claims 1-5, 17, 19 and 20 are rejected under 35 U.S.C. Section 112, first paragraph as not being enabled by the specification. The Examiner says that the specification is enabling for a method of treating cholesterol disorders with an intermediate release composition comprising nicotinic acid, which exhibits a specific dissolution profile manufactured by wet granulation of hydroxypropyl methylcellulose, povidone and stearic acid. However, the Examiner argues that the specification is not enabling for the claimed method using "any" pharmaceutical delivery system so as to achieve the claimed *in vitro* dissolution profile. Applicants respectfully traverse.

Claims 1-5, 17, 19 and 20 have all been canceled. Applicants wonder if the Examiner has made a typographical error and means to refer to claims 29-36 and 38-61. Applicants will now address this rejection with respect to claims 29-36 and 38-61.

As discussed in *MPEP* Section 2164.01, any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. In order to make an enablement rejection, the initial burden is on the Examiner to establish a reasonable basis to question the enablement provided for the claimed invention (See *MPEP* Section 2164.04; citing, *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Moreover, according to *MPEP* Section 2164.04, a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Applicants submit that the Examiner has not met her burden to establish a reasonable basis to question the enablement of the claimed invention as currently amended. Applicants submit that the specification teaches one skilled in the art how to make and use the invention that is commensurate with the scope of the claims. Specifically, claim 29, which is the only independent claim, has been amended to recite that the intermediate release formulation

comprises 1000 mg of nicotinic acid and a swelling agent. The specification on page 24, beginning at line 16 – page 25, line 5 describes in detail the swelling agent that can be used to make the claimed formulation. A number of examples of swelling agents, such as carboxymethylcellulose, methylcellulose, waxes (such as bees wax), natural materials (like gums or gelatins) or mixtures thereof are provided. Additionally, Applicants disagree with the Examiner's assertion that the specification is only enabling for formulations containing povidone and stearic acid. Povidone and stearic acid are commonly used excipients that are routinely employed in pharmaceutical formulations. Specifically, it is known in the pharmaceutical arts that povidone functions as a binder and stearic acid functions as a lubricant. The use of these excipients in formulations does not affect the release rate of the active ingredient from the formulation. Because excipients are routinely employed in pharmaceutical formulations, one skilled in the art would easily be able to select the appropriate excipients, such as a binder and a lubricant, for use in the formulations of the present invention to provide the claimed dissolution rate as recited in claim 1 without undue experimentation. Finally, the general experimental section of the specification, beginning on the bottom of page 25, provides a detailed description of how to make the claimed invention. Thus, the claimed invention is adequately enabled by the specification. In view thereof, this rejection is now moot and should be withdrawn.

Claim Rejections – 35 U.S.C. Section 102(b)

Claims 29-36 and 38-61 are rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent No. 5,268,181 to O'Neill et al. ("'181"). According to the Examiner, '181 teaches a composition comprising niacin in the claimed amounts for treating hyperlipidemia. The Examiner says that the composition is administered in the evening, very similar to the present invention. The Examiner further states that "'181 teaches the same delivery system as that described in the instant claims i.e., HPMC, magnesium stearate etc (see examples). While '181 does not mention the dissolution factors and profiles of instant claims, both '181 and instant claims are directed to the same method of treatment with the same composition and hence the claimed dissolution pattern is inherent to the composition of '181." Applicants respectfully traverse.

As discussed previously herein, the "Related Patent Application" information on page 1 of the above application has been amended reflect that priority of the present application is claimed back to U.S. Application No. 08/124,392 filed on September 20, 1993. Therefore, because U.S. Patent No. 5,268,181 issued on December 7, 1993, Applicants submit that this patent is not 35 U.S.C. Section 102(b) prior art. However, in anticipation of a possible 35 U.S.C. Section 102(e) rejection being made by the Examiner, Applicants herewith enclose a Declaration Under 37 CFR Sections 1.131 of David J. Bova (hereinafter "Bova Declaration"). Applicants successfully removed U.S. Patent No. 5,268,181 as prior art in the parent, grandparent and sister cases with the Bova Declaration (hereinafter the "Original Bova Declaration").

The Examiner will note that in paragraph 2 of the Bova Declaration, reference is mistakenly made to the Office Action rejecting the above application under 35 U.S.C. Section 102(e). Applicants would also like to point out that certain paragraphs in the Bova Declaration reference results being disclosed in the "above-captioned application and in the parent application in Table II" (See for example, Paragraph 5). Applicants would like to make it clear to the Examiner that while working on the Bova Declaration several errors in the data were found in Table II in the above-captioned application and in the parent application. The Table II marked "revised" in the attached Bova Declaration contains the corrected data (note: Applicants amended the Table II in the specification of the instant application as well.) Applicants would like to emphasize that the corrected data contained in "revised" Table II does not in any way affect any of the conclusions to be drawn in the above application or in any of the parent applications.

In view of the submission of the Bova Declaration, Applicants submit that U.S. patent No. 5,268,181 is not prior art under 35 U.S.C. Sections 102(b) or 102(e). In view thereof, this rejection should be removed.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned at (847) 935-7956.

Respectfully submitted,
Cefali, et al.

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/Johanna M. Corbin/
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Registration No. 51,582
Attorney for Applicants

EXHIBIT A

PTO/SB/96 (12-05)
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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Kos Pharmaceuticals, Inc.

Application No./Patent No./Control No.: 08/960,557 Filed/Issue Date: October 31, 1997

Entitled: Methods for Treating Hyperlipidemia With Intermediate Release Nicotinic Acid Compositions Having Unique Biopharmaceutical Characteristics

Kos Pharmaceuticals, Inc., a Corporation
(Name of Assignee) (Type of Assignee: corporation, partnership, university, government agency, etc.)

states that it is:

1. ☑ the assignee of the entire right, title, and interest; or

2. ☐ an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is _____%)

in the patent application/patent identified above by virtue of either:

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 9035, Frame 0157, or a true copy of the original assignment is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
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2. From: _____ To: _____
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3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Andrew I. Koven/	Jan. 12, 2006
Signature	Date
Andrew I. Koven	609-495-0530
Printed or Typed Name	Telephone Number
Executive Vice President	
Title	

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EXHIBIT B

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Patent Assignment Abstract of Title

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Total Assignments: 2

Patent #: 6080428 **Issue Dt:** 06/27/2000 **Application #:** 08368378 **Filing Dt:** 01/14/1995

Inventor: DAVID J. BOVA

Title: NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA AND RELATED METHODS THEREFOR

Assignment: 1

Reel/Frame: 007378/0625 **Recorded:** 03/06/1995 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: BOVA, DAVID J. **Exec Dt:** 12/31/1994

Assignee: KOS PHARMACEUTICALS, INC.
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MIAMI,, FLORIDA

Correspondent: REESE TAYLOR
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AKRON, OH 44308

Assignment: 2

Reel/Frame: 018061/0819 **Recorded:** 08/08/2006 **Pages:** 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: KOS PHARMACEUTICALS, INC. **Exec Dt:** 08/08/2006

Assignee: KOS LIFE SCIENCES, INC.
2100 NORTH COMMERCE PARKWAY
WESTON, FLORIDA 33326

Correspondent: KOS PHARMACEUTICALS, INC
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CRANBURY, NJ 08512-3618

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Total Assignments: 2

Patent #: 6129930 **Issue Dt:** 10/10/2000 **Application #:** 08814974 **Filing Dt:** 03/06/1997

Inventor: DAVID J. BOVA

Title: METHODS AND SUSTAINED RELEASE NICOTINIC ACID COMPOUNDS FOR TREATING HYPERLIPIDEMIA AT NIGHT

Assignment: 1

Reel/Frame: 010844/0370 **Recorded:** 05/31/2000 **Pages:** 4

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: BOVA, DAVID J. **Exec Dt:** 05/17/2000

Assignee: KOS PHARMACEUTICALS, INC.
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Assignment: 2

Reel/Frame: 018061/0819 **Recorded:** 08/08/2006 **Pages:** 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: KOS PHARMACEUTICALS, INC. **Exec Dt:** 08/08/2006

Assignee: KOS LIFE SCIENCES, INC.
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Total Assignments: 4

Patent #: 6469035 **Issue Dt:** 10/22/2002 **Application #:** 08903755 **Filing Dt:** 07/31/1997

Inventor: EUGENIO A. CEFALI

Title: METHODS OF PRETREATING HYPERLIPIDEMIC INDIVIDUALS WITH A FLUSH INHIBITING AGENT PRIOR TO THE START OF SINGLE DAILY DOSE NICOTINIC ACID THERAPY TO REDUCE FLUSHING PROVOKED BY NICOTINIC ACID

Assignment: 1

Reel/Frame: 014043/0201 **Recorded:** 10/10/2003 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: CEFALI, EUGENIO **Exec Dt:** 10/09/2003

Assignee: KOS PHARMACEUTICALS, INC.
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Assignment: 2

Reel/Frame: 014669/0316 **Recorded:** 10/15/2003 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: CEFALI, EUGENIO **Exec Dt:** 10/09/2003

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Assignment: 3

Reel/Frame: 015400/0181 **Recorded:** 10/15/2003 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: CEFALI, EUGENIO **Exec Dt:** 10/09/2003

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Assignment: 4

Reel/Frame: 018454/0243 **Recorded:** 10/31/2006 **Pages:** 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: KOS PHARMACEUTICALS, INC. **Exec Dt:** 10/30/2006

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Total Assignments: 3

Patent #: 6406715 **Issue Dt:** 06/18/2002 **Application #:** 08962423 **Filing Dt:** 10/31/1997

Inventor: EUGENIO A. CEFALI

Title: INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA HAVING UNIQUE URINARY METABOLITE PROFILES

Assignment: 1

Reel/Frame: 009080/0542 **Recorded:** 04/03/1998 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: CEFALI, EUGENIO A. **Exec Dt:** 03/18/1998

Assignee: KOS PHARMACEUTIALS, INC.
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Assignment: 2

Reel/Frame: 013525/0665 **Recorded:** 11/13/2002 **Pages:** 6

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: BOVA, DAVID J. **Exec Dt:** 11/12/2002

Assignee: KOS PHARMACEUTICALS, INC.
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Assignment: 3

Reel/Frame: 017240/0116 **Recorded:** 11/18/2005 **Pages:** 12

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: KOS PHARMACEUTICALS, INC. **Exec Dt:** 08/01/2003

Assignee: KOS LIFE SCIENCES, INC.
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Total Assignments: 2

Patent #: 6746691 **Issue Dt:** 06/08/2004 **Application #:** 08962424 **Filing Dt:** 10/31/1997

Publication #: 20010014338 **Pub Dt:** 08/16/2001

Inventor: EUGENIO A. CEFALI

Title: INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA HAVING UNIQUE BIOPHARMACEUTICAL CHARACTERISTICS

Assignment: 1

Reel/Frame: 009080/0033 **Recorded:** 04/03/1998 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: CEFALI, EUGENIO A. **Exec Dt:** 03/18/1998

Assignee: KOS PHARMACEUTICALS, INC.
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Assignment: 2

Reel/Frame: 017240/0116 **Recorded:** 11/18/2005 **Pages:** 12

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: KOS PHARMACEUTICALS, INC. **Exec Dt:** 08/01/2003

Assignee: KOS LIFE SCIENCES, INC.
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Patent Assignment Abstract of Title

NOTE:Results display only for issued patents and published applications. For pending or abandoned applications please consult USPTO staff.

Total Assignments: 2

Patent #: 6818229 **Issue Dt:** 11/16/2004 **Application #:** 08962027 **Filing Dt:** 10/31/1997

Inventors: DAVID J. BOVA, EUGENIO A. CEFALI

Title: INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA

Assignment: 1

Reel/Frame: 009080/0471 **Recorded:** 04/03/1998 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: CEFALI, EUGENIO A. **Exec Dt:** 03/18/1998

Assignee: KOS PHARMACEUTICALS, INC.
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Assignment: 2

Reel/Frame: 017240/0116 **Recorded:** 11/18/2005 **Pages:** 12

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: KOS PHARMACEUTICALS, INC. **Exec Dt:** 08/01/2003

Assignee: KOS LIFE SCIENCES, INC.
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Total Assignments: 3

Patent #: 7011848 **Issue Dt:** 03/14/2006 **Application #:** 09470603 **Filing Dt:** 12/22/1999

Inventor: David J. Bova

Title: NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA AND RELATED METHODS THEREFOR

Assignment: 1

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Assignment: 2

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Assignment: 3

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